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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/809,738	03/25/2004	Steven Stice	04342.105062 CON	8182

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EXAMINER	
CROUCH, DEBORAH	
ART UNIT	PAPER NUMBER
1632	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	04/24/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/809,738	STICE, STEVEN	
	Examiner	Art Unit	
	Deborah Crouch, Ph.D.	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 March 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-5 and 7-30* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5 and 7-30* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Applicant's arguments filed March 5, 2007 have been fully considered but they are not persuasive. The amendment has been entered. Claims 1-5 and 7-30 are pending.

Applicant's amendments have overcome the rejection made in the office action mailed August 31, 2006 under 35 U.S.C. § 102(b).

Applicant's amendments and arguments have overcome the rejection made in the office action mailed August 31, 2006 under 35 U.S.C. 103(a) as being unpatentable over Prather et al. (1989) Biology of Reproduction, Vol. 41, pp. 414-418 in view of Kwon et al. (1996) Proced. Natl. Acad. Sci., Vol. 93, pp. 13010-13013.

Applicant's amendments and arguments have overcome the rejection made in the office action mailed August 31, 2006 under 35 U.S.C. 103(a) as being unpatentable over of Kwon et al. (1996) Proced. Natl. Acad. Sci., Vol. 93, pp. 13010-13013 in view of Campbell et al (1994) Biology of Reproduction, Vol. 50, pp. 1385-1393.

Applicant's amendments and arguments have overcome the rejection made in the office action mailed August 31, 2006 under 35 U.S.C. 103(a) as being unpatentable over Kwon et al. (1996) Proced. Natl. Acad. Sci., Vol. 93, pp. 13010-13013 in view of Yang et al, (1992) Biol. Reprod. 46, suppl. No. 1, page 117, Abs. 268.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-5 and 7-30 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of producing a cloned nonprimate mammalian NT embryo comprising introducing a donor metaphase differentiated cell or nucleus from a donor metaphase cell into a metaphase oocyte to form a reconstructed

oocyte, activating the oocyte to form a nonprimate mammalian embryo and a method of producing a cloned nonprimate mammal comprising introducing a donor metaphase differentiated cell or nucleus from a donor metaphase cell into a metaphase oocyte to produce a reconstituted oocyte, activating the oocyte to form a nonprimate mammalian embryo, where the differentiated cell is selected from the group consisting of fibroblast, an epithelial cell and a hematopoietic cell, does not reasonably provide enablement for a method of producing a cloned nonhuman mammalian NT embryo or a method of producing a cloned nonhuman mammal. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The claims are to "method of producing a cloned nonhuman, non-primate mammalian NT embryo." An embryo means the structure has the ability to divide and develop into a multicellular embryo, a blastocyst, or a mammal. However, unless the oocyte is activated or fused the NT embryo will not so develop. The claims as presently written are not limited to an embryo but to an NT unit (See specification, page 6, lines 12-22).

Further, the oocyte used in the presently claimed invention would need to be a metaphase oocyte. The reasoning is during metaphase, MPF activity is highest and exposure of the donor nucleus to MPF permits nuclear reprogramming and remodeling (Campbell, page 246, col. 2, lines 14-35).

Claim 7 is not enabled for "lymphocyte." Lymphocytes are comprised of rearranged genomes and thus are not capable of producing a full panoply of B- and T-lymphocytes. This does not reflect the production of a cloned mammal. The mammal from which the particular lymphocyte was isolated would be capable of producing many different types of B- and T-lymphocytes as part of an immune response.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 9 is vague as to the metes and bounds of "late embryonic stage." It isn't clear from the specification when an embryo is at a late stage.

Claim 13 is vague as to the metes and bounds of "about the same time." The breadth of about isn't defined in the specification.

Claims 26 and 27 both contain "nonhuman mammalian NT embryo," which is broader than "nonhuman, nonprimate mammal."

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 7, 9, 10 and 24 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Cibelli et al (1998) Science, Vol. 280, pp. 1256-1258 in view of Kwon et al. (1996) Proced. Natl. Acad. Sci., Vol. 93, pp. 13010-13013 for reasons set forth in the office action mailed August 31, 2006.

Applicant argues there is nothing in either reference that metaphase donor genetic mater from a differentiated cells could be successfully used as the source of genetic material in a nuclear transfer operation. Applicant argues there is nothing in the references that the donor cells could be both differentiated and in metaphase, and still give rise to successful

nuclear transfer. Applicant argues Kwon clearly gives preference for undifferentiated donor genetic material at the 4-cell stage. Applicant argues Cibelli states more work is necessary to allow for reprogramming and full term development of offspring. Applicant argues two years exist between Kwon and Cibelli, yet Cibelli drew no conclusions from Kwon. Applicant argues the worker of ordinary skill would most likely attribute the difference in success rates to the differences in donor cells, embryonic versus somatic. These arguments are not persuasive.

The claims rejected are only to the production of NT embryos. Thus, for the production of embryos alone, the success rate of Kwon in sufficient to motivate the skilled artisan to modify Cibelli through the use of differentiated metaphase cells as nuclear donors. Further, the present claims do not require an improvement or a certain number of embryos to be formed. One would be sufficient. There is sufficient teachings and guidance for producing one NT embryo. Again, it is noted the claims are actually to NT units, and not embryos (see enablement, above.) The comments by Cibelli, cited by applicant, are additional motivation to use metaphase donor cells to develop methods for reprogramming donor cells for more efficient nuclear transfer protocols. As applicant is aware, the length of time between publications has no bearing on the appropriateness of cited art. No single author can be expected to recognize and account for all publications prior to their reference.

Claims 1, 7-10 and 24 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Wakayama et al (1998) Nature, Vol. 394, pp. 369-374 in view of Kwon et al. (1996) Proced. Natl. Acad. Sci., Vol. 93, pp. 13010-13013 for reasons set forth in the office action mailed August 31, 2006.

Applicant argues there is nothing in either reference that metaphase donor genetic mater from a differentiated cells could be successfully used as the source of genetic material in a nuclear transfer operation. Applicant argues there is nothing in the references that the

donor cells could be both differentiated and in metaphase, and still give rise to successful nuclear transfer. Applicant argues Kwon clearly gives preference for undifferentiated donor genetic material at the 4-cell stage. Applicant argues Wakayama states a preference for G0 of G1 donor genetic material. Applicant argues that Wakayama states previous studies indicated embryonic development is enhanced when donor nuclei are in G0 or G1. Applicant argues two years exist between Wakayama and Kwon, yet Wakayama drew no conclusions from Kwon. Applicant argues the worker of ordinary skill would most likely attribute the difference in success rates to the differences in donor cells, embryonic versus somatic. These arguments are not persuasive.

The claims rejected are only to the production of NT embryos; not production of cloned animals. Thus, for the production of embryos alone, the success rate of Kwon in sufficient to motivate the skilled artisan to modify Wakayama through the use of differentiated metaphase cells as nuclear donors even though Wakayama states the art believed G1 or G0 cells were best as nuclear donors. This is entirely predicated on the ordinary artisan reading Kwon, seeing the enhanced rate of nuclear transfer, and would be so motivated to combine. Further, the present claims do not require an improvement or a certain number of embryos to be formed. One would be sufficient. There is sufficient teachings and guidance for producing one NT embryo. Again, it is noted the claims are actually to NT units, and not embryos (see enablement, above.) As applicant is aware, the length of time between publications has no bearing on the appropriateness of cited art. No single author can be expected to recognize and account for all publications prior to their reference.

Claims 2-5 and 11-30 are free of the prior art.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deborah Crouch, Ph.D. whose telephone number is 571-272-0727. The examiner can normally be reached on M-Fri, 6:00 AM to 3:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter Paras can be reached on 571-272-4517. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Deborah Crouch, Ph.D.
Primary Examiner
Art Unit 1632

April 20, 2007